IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

MSN LABORATORIES PRIVATE LIMITED,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 1:23-cv-1675
	)	
BIOPROJET SOCIÉTÉ CIVILE DE RECHERCHE,	)	
	)	
	)	
Defendant.	)	
	)	
	)	

MEMORANDUM IN SUPPORT OF DEFENDANT BIOPROJET SCR'S MOTION TO TRANSFER THIS ACTION TO THE DISTRICT OF DELAWARE OR STAY PROCEEDINGS

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INTRODUCTION

Defendant Bioprojet Société Civile de Recherche ("Bioprojet SCR") respectfully requests that the Court transfer this action to the United States District Court for the District of Delaware pursuant to 28 U.S.C. § 1404(a) or, in the alternative, stay this action until parallel proceedings pending in the District of Delaware are resolved.

The present dispute can and should be resolved along with three related actions currently pending in the District of Delaware. Bioprojet SCR, Bioprojet Pharma SAS ("Bioprojet Pharma") (collectively, "Bioprojet"), and Harmony Biosciences, LLC ("Harmony") brought the three Delaware actions pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 ("the Hatch-Waxman Act") against seven different generic applicants (including MSN Laboratories Private Ltd.), all seeking to market copies of Bioprojet and Harmony's drug WAKIX®. The Delaware actions involve the same three patents at issue in this litigation. Indeed, at the time MSN Laboratories Private Ltd. ("MSN") filed the present action, Bioprojet and Harmony had already filed two of the Delaware actions, against six generic filers, in the District of Delaware. One business day after Bioprojet and Harmony learned of MSN's Abbreviated New Drug Application ("ANDA") from the filing of this declaratory judgment action, they likewise filed an infringement action against MSN and MSN's U.S. Agent (MSN Pharmaceuticals Inc.) in the District of Delaware. Bioprojet SCR thus seeks transfer of this case to the judicial district in which comprehensive patent litigation on these patents is pending.

The factors courts consider under 28 U.S.C. § 1404(a) strongly support transfer. As an initial matter and as explained below, MSN's declaratory judgment claims are improper because MSN failed to follow the statutory and regulatory requirements necessary to bring them. Even if MSN were permitted to bring this action, it should have been filed in Delaware, and the interests of justice dictate transfer. Harmony, the exclusive licensee of the patents at issue and the holder of

New Drug Application ("NDA")[1] No. 211150 for WAKIX®, is missing from this action, presumably because, as a Delaware company with no physical presence in Virginia, its inclusion would have been improper in this district. This action likewise excludes Bioprojet Pharma, a wholly-owned subsidiary of Bioprojet SCR involved in the commercialization efforts of WAKIX®; and MSN Pharmaceuticals Inc., MSN's U.S. Agent, also incorporated in Delaware.

Neither MSN nor Bioprojet SCR is incorporated in Virginia or has a principal place of business in Virginia. Compl. ¶¶ 9, 10. MSN cannot assert any legitimate interest in having the Eastern District of Virginia—rather than Delaware—resolve this dispute. If this action is transferred to Delaware, it will be litigated alongside the related Delaware action between Bioprojet, Harmony, and MSN, as well as two related actions against six other generic companies involving the same patents. All three Delaware actions have been assigned to the same judge, Judge Maryellen Noreika. Bioprojet and Harmony plan to seek consolidation of the Delaware actions and anticipate that the actions will proceed in a coordinated manner. Transfer will avoid the possibility of inconsistent judicial determinations concerning claim construction, infringement, and validity of these patents. It will also avoid the unnecessary waste of resources for the parties, and more importantly, the courts, if these cases were to proceed separately at the same time in two different venues. Given the common legal and factual issues, transfer of this case to the District of Delaware will serve the interests of judicial economy and convenience of the parties and witnesses, consistent with the policies that underlie § 1404(a).

Alternatively, the Court should stay this declaratory judgment action in the interest of efficient litigation while the parallel litigation proceeds in the District of Delaware.

[1] The NDA is the vehicle through which drug sponsors formally propose that the Food and Drug Administration ("FDA") approve a new pharmaceutical for sale and marketing in the United States.

FACTUAL BACKGROUND

WAKIX® is a first-in-class drug indicated for the treatment of excessive daytime sleepiness ("EDS") or cataplexy in adult patients with narcolepsy. Narcolepsy is a debilitating disease that can severely affect a patient's day-to-day functioning and can have a devastating impact on quality of life. WAKIX®'s active ingredient, pitolisant hydrochloride, is an antagonist/inverse agonist of the histamine-3 (H3) receptor. WAKIX® is the result of work by Bioprojet SCR, Bioprojet Pharma, and Harmony. Bioprojet SCR is the assignee and owner of the patents at issue here. *See Harmony Biosciences, LLC v. MSN Pharms. Inc.*, C.A. No. 23-1420-MN (D. Del. Dec. 11, 2023), Dkt. 1 ¶ 15. Bioprojet Pharma is a wholly-owned subsidiary of Bioprojet SCR, and was involved in commercialization efforts. *Id.* ¶ 16. Harmony is the exclusive licensee of the patents at issue and the holder of NDA No. 211150 for WAKIX®. *Id.* ¶ 14. Harmony is engaged in the clinical development of WAKIX® and sells WAKIX® in the United States. *Id.*

WAKIX® received FDA approval on August 14, 2019. It is the first FDA-approved H3 receptor antagonist/inverse agonist and the first and only FDA-approved once-daily tablet for treatment of EDS and cataplexy in narcolepsy. WAKIX® was granted orphan drug exclusivity—a seven-year regulatory exclusivity granted to drugs that treat rare diseases or conditions, *see* 21 C.F.R. § 316—for the treatment of EDS in adult patients with narcolepsy and for the treatment of cataplexy in adult patients with narcolepsy. WAKIX®'s orphan drug exclusivities for the treatment of EDS in adult patients with narcolepsy and for the treatment of cataplexy in adult patients with narcolepsy expire on August 14, 2026 and October 13, 2027, respectively.

United States Patent Nos. 8,486,947 ("the '947 patent"); 8,207,197 ("the '197 patent"); and 8,354,430 ("the '430 patent) (collectively, "the patents-in-suit") are listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book)

for WAKIX®. Ex. 1 (WAKIX® Orange Book Listing).[2] To date, seven companies (Lupin Limited, Novugen Pharma Sdn. Bhd., AET Pharma US Inc., Annora Pharma Private Limited, Novitium Pharma LLC, Zenara Pharma Private Limited, and MSN Laboratories Private Limited) have filed ANDAs seeking approval for generic versions of WAKIX® with so-called Paragraph IV certifications asserting that some or all of the Orange Book patents for WAKIX® are invalid and/or will not be infringed.

On November 9, 2023, Harmony, Bioprojet SCR, and Bioprojet Pharma filed suit in the United States District Court for the District of Delaware against Lupin Limited, Lupin Pharmaceuticals, Inc.; Novugen Pharma Sdn. Bhd., Novugen Pharma (USA) LLC, and Makro Technologies Inc. for infringement of the '947 and '197 patents. *See Harmony Biosciences, LLC et al. v. Lupin Limited et al.*, C.A. No. 23-1286-MN (D. Del. Nov. 9, 2023). On November 21, 2023, Harmony, Bioprojet SCR, and Bioprojet Pharma filed a second suit in that same court against AET Pharma US, Inc.; Annora Pharma Private Limited, Hetero USA, Inc., Hetero Labs Limited; Novitium Pharma LLC; Zenara Pharma Private Limited, and Biophore India Pharmaceuticals Private Limited for infringement of one or more of the '947, '197, and '430 patents. *See Harmony Biosciences, LLC et al. v. AET Pharma US, Inc. et al.*, C.A. No. 23-1340-MN (D. Del. Nov. 21, 2023).

On Friday, December 8, 2023, MSN Laboratories Private Limited filed the present action in this Court solely against Bioprojet SCR "based on MSN's filing of an Abbreviated New Drug Application No. 218873," Compl. at 1, through which MSN is seeking FDA approval to sell generic versions of the pharmaceutical product WAKIX® (pitolisant hydrochloride) tablets prior to the expiration of the patents-in-suit. MSN seeks a declaratory judgment that the patents-in-suit

[2] All exhibits are appended to the supporting Declaration of Erica N. Andersen.

are invalid and/or will not be infringed by MSN's proposed generic pitolisant hydrochloride product. *See* Compl. at 1. MSN did not name Harmony, a Delaware company, as a defendant in its declaratory judgment action. MSN also did not name its own U.S. Agent, MSN Pharmaceuticals, Inc., which is likewise a Delaware company.

Through the filing of MSN's December 8, 2023 complaint, Bioprojet and Harmony became aware of MSN's ANDA. In that complaint, MSN alleged that it provided notice by sending a letter via Federal Express on October 13, 2023. Compl. ¶ 29. Attached to MSN's complaint as Exhibit D was a single Federal Express delivery confirmation of MSN's notice letter to Harmony. Compl., Ex. D. Based on the information in MSN's complaint, Bioprojet SCR and Harmony initiated investigations to determine whether they had received proper notice from MSN consistent with the requirements of 21 U.S.C. §§ 355(b)(3), (j)(2)(B), and 21 C.F.R. § 314.95. Harmony was able to determine that it received a letter dated October 13, 2023 from MSN. However, the Harmony employee who received the letter did not understand its import and did not forward it to the legal department.

The first page of the letter received by Harmony has two addressees—Harmony itself and Bioprojet Pharma. The October 13 letter did not include the patent holder, Bioprojet SCR, as an addressee—despite the body of the letter listing "Bioprojet SC" as the patent owner. Ex. 2 (MSN Letter) at 1, 3. Nor was the letter addressed to the correct address for Bioprojet SCR listed with the Patent and Trademark Office ("USPTO"), 30 rue des Francs Bourgeois, 75003 Paris, France. Ex. 3 (USPTO Assignment Database Listings).

In light of their dispute with MSN regarding infringement and validity of the patents-in-suit, on Monday, December 11, 2023, Bioprojet SCR, Bioprojet Pharma, and Harmony filed a complaint for infringement of the patents-in-suit against MSN and MSN Pharmaceuticals Inc., in

the District of Delaware. *See Harmony Biosciences, LLC et al. v. MSN Pharms. Inc. et al.*, C.A. No. 23-1420-MN (D. Del. Dec. 11, 2023). The infringement suit was designated as related to the other pending District of Delaware suits concerning the same patents and assigned to Judge Maryellen Noreika. Regardless of the outcome of any pending suits, FDA cannot approve MSN's ANDA until at least August 14, 2026 due to regulatory exclusivity, specifically orphan drug exclusivity for treatment of excessive daytime sleepiness in patients with narcolepsy.

LEGAL BACKGROUND

The dispute here relates to MSN's request for approval of a generic WAKIX® product under the Hatch-Waxman Act. The Hatch-Waxman Act permits a generic drug manufacturer to seek FDA approval to sell a generic version of a previously approved drug (in this case, WAKIX®) by submitting an ANDA. An ANDA filer benefits from a short-cut: instead of conducting its own costly clinical trials—as would be required without this abbreviated pathway—it can obtain FDA approval by relying on the previous approval of an innovator drug, as long as the ANDA filer shows that its products are "bioequivalent" to that previously approved drug. 21 U.S.C. § 355(j)(2)(A)(iv).

Every ANDA must include a statement, or "certification," regarding the patent status of the FDA-approved drug that the ANDA uses as a reference. *See id.* § 355(j)(2)(A)(vii). The Orange Book lists the patents that the owner of the FDA-approved product believes cover its active pharmaceutical ingredient, drug product, and/or approved uses. If an ANDA filer wants to market a generic drug before an Orange Book-listed patent covering the brand name drug has expired, that filer must certify the patent is invalid and/or that the proposed generic product will not infringe the patent. *See id.* § 355(j)(2)(A)(vii)(IV). This is known as a "Paragraph IV Certification." Notice of a Paragraph IV Certification must be sent to the owner of each patent that is the subject of the certification, as well as the NDA holder for the reference FDA-approved drug. *See id.*

§§ 355(j)(2)(B)(iii). This "Notice Letter" must contain a detailed statement providing the reasons the generic company believes each patent is invalid or will not be infringed, *id.* §§ 355(j)(2)(B)(iv)(II), as well as an Offer of Confidential Access to the ANDA, *id.* §§ 355(j)(5)(C)(i)(III), so that the patentee and NDA holder can evaluate the statements in the Notice Letter.

So that the disputed patent rights may be resolved before FDA approves the ANDA, the Hatch-Waxman Act made the act of filing an ANDA with a Paragraph IV Certification an act of patent infringement. *See* 35 U.S.C. § 271(e)(2). Specifically, the patent owner may sue the ANDA filer for patent infringement after receiving notification of the Paragraph IV Certification. Typically, if the owner files suit within forty-five days, FDA may not approve the ANDA for thirty months, until the ANDA filer prevails in the suit, or until otherwise ordered by the Court. For FDA approved drugs that are New Chemical Entities (such as WAKIX®), this thirty-month period "shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the [NDA]." 21 U.S.C. 355(j)(5)(F)(ii). Accordingly, in the Delaware actions initiated by Bioprojet SCR, Bioprojet Pharma, and Harmony against generic manufacturers seeking to market copies of WAKIX®, the stay lasts until February 14, 2027, 7.5 years from WAKIX®'s approval date.

The ANDA filer is forbidden by statute from seeking declaratory relief until at least 45 days after it has provided the Notice Letter to the patent owner and NDA holder. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa).

ARGUMENT

28 U.S.C. § 1404(a) serves "to prevent the waste 'of time, energy and money' and 'to protect litigants, witnesses and the public against unnecessary inconvenience and expense.'" *Van Dusen v. Barrack*, 376 U.S. 612, 616 (1964) (quoting *Cont'l Grain Co. v. Barge F.B.L.-585*, 364

U.S. 19, 26–27 (1960)); *see* 28 U.S.C. § 1404(a) ("For the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought or to any district or division to which all parties have consented.").

As a threshold matter, a movant seeking transfer must show "that personal jurisdiction and venue would have been proper in the transferee forum." *Noetic Specialty Ins. Co. v. N.C. Mut. Wholesale Drug Co.*, 453 F. Supp. 3d 842, 844 (E.D. Va. 2020). Once this threshold requirement is satisfied, the district court has "broad discretion" to decide whether to transfer a civil action to another district. *In re Juniper Networks, Inc.*, 14 F.4th 1313, 1318 (Fed. Cir. 2021); *Gibbs v. Haynes Investments, LLC*, 368 F. Supp. 3d 901, 918 (E.D. Va. 2019). "In determining whether to grant a motion to transfer under § 1404(a), a court considers and balances a variety of factors, including (i) the weight accorded to plaintiff's choice of venue; (ii) witness convenience and access; (iii) convenience of the parties; and (iv) the interest of justice." *Noetic*, 453 F. Supp. 3d at 845.

Here, all four factors favor transferring the present case to the District of Delaware.

I. Venue and Personal Jurisdiction Are Proper in the District of Delaware.

As a threshold matter, this Court can transfer this action to the District of Delaware, because it unquestionably "might have been brought" there. 28 U.S.C. § 1404(a). Venue is proper in the District of Delaware because Defendant Bioprojet SCR is a foreign entity, *see* Compl. ¶ 10, so it "may be sued in any judicial district," including the District of Delaware. 28 U.S.C. § 1391(c)(3); *In re HTC Corp.* 889 F.3d 1349, 1356 (Fed. Cir. 2018) (affirming that venue laws do not restrict where a foreign corporation may be sued following *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1520 (2017)). The District of Delaware may exercise personal jurisdiction over Bioprojet SCR in this matter because Bioprojet SCR has sufficient

minimum contacts with the district and has availed itself of the forum in connection with the WAKIX® patents by bringing several related Hatch-Waxman actions in the district. *See Harmony Biosciences, LLC et al. v. MSN Pharms. Inc. et al.*, C.A. No. 23-1420-MN (D. Del. Dec. 11, 2023); *Harmony Biosciences, LLC et al. v. Lupin Limited et al.*, C.A. No. 23-1286-MN (D. Del. Nov. 9, 2023); *Harmony Biosciences, LLC et al. v. AET Pharma US, Inc. et al.*, C.A. No. 23-1340-MN (D. Del. Nov. 21, 2023). Bioprojet SCR will not contest personal jurisdiction or venue with respect to MSN's counterclaims if they are transferred to the District of Delaware.

II. Convenience and the Interest of Justice Warrant Transfer.

A. MSN's Choice of Forum Should Be Given No Weight Because This Action Was Not Properly Initiated, Has No Connection With This District, and Omits a Key Party Not Subject to Jurisdiction and Venue in This District.

MSN's choice of forum should be given no weight for several reasons.

First, MSN failed to provide proper notice to the patent owner and NDA holder, which is a statutory prerequisite to bring a declaratory judgment action under the Hatch-Waxman Act. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa). As MSN was not entitled to bring this action under the statute, its choice of forum should be given no weight.

MSN was required to send notice of its Paragraph IV Certification to the patent owner ***as well as*** the NDA holder. *See* 21 U.S.C. §§ 355(j)(2)(B)(iii). The related regulation states that the "[t]he name and address of the patent owner or its representative may be obtained from the U.S. Patent and Trademark Office." 21 CFR § 314.95(a)(1). Although MSN claims it gave notice to the patent holder (Bioprojet SCR), the FedEx delivery confirmation appended to its complaint shows delivery of its October 13 letter to Harmony (the NDA holder). *See* Compl., Ex. D. In its complaint, MSN provides no documentation indicating Bioprojet SCR received a copy of the letter.

This omission is not surprising. A review of the October 13 letter reveals a number of deficiencies. The addressees of the letter are Harmony—the NDA holder—and Bioprojet

Pharma—a separate entity from patent holder Bioprojet SCR. Ex. 2 (MSN Letter) at 1. Although MSN appears to understand Bioprojet SCR is the patent owner—the letter itself later lists "Bioprojet SC" as the patentee, and MSN sued Bioprojet SCR—it failed to address the letter to the proper Bioprojet entity. Ex. 2 (MSN Letter) at 1, 3. Moreover, the letter did not include (and apparently was not sent to) the address for Bioprojet SCR listed with the USPTO (30 rue des Francs Bourgeois, 75003 Paris, France). Ex. 3 (USPTO Assignment Database Listings). Thus, MSN has not provided the requisite notice to both the patent owner, Bioprojet SCR, and the NDA holder, Harmony, and the 45-day period to file an infringement suit has not expired. 21 U.S.C. § 355(j)(5)(B)(iii); *see also* Compl. ¶ 7 ("After ***both*** the patent owner and NDA holder have received the Paragraph IV notice letter, they have forty-five days to file suit asserting infringement....") (emphasis added). Because the 45-day period has not expired, there is no jurisdiction for this declaratory judgment action. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa) (stating that no action may be brought under the Declaratory Judgment Act unless "the 45-day period referred to in [21 U.S.C. § 355(j)(5)(B)(iii)] has expired").

Second, even if MSN's action were proper (it is not), Virginia is not the home forum for MSN Laboratories Private Limited nor Bioprojet SCR, and the cause of action bears no relation to this forum. The complaint alleges that MSN Laboratories Private Limited is a company organized and existing under the laws of India, with a principal place of business in Hyderabad, Telangana, India. Compl. ¶ 9. MSN does not allege that it has a physical presence in Virginia nor that any of the underlying infringement acts regarding the submission of its ANDA occurred in this state. The Supreme Court has held that a plaintiff's forum choice "applies with less force" when the "plaintiff's choice is not its home forum." *Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 430 (2007); *Piper Aircraft Co. v. Reyno*, 454 U.S. 235, 256 (1981) (stating that when

a plaintiff is foreign, the presumption of favor for its choice of forum is "less reasonable"). This court has transferred patent cases when "Virginia is not the home forum of either plaintiff or defendant" and the "cause of action bears little relation to this forum." *Telepharmacy Sols., Inc. v. Pickpoint Corp*., 238 F. Supp. 2d 741, 743 (E.D. Va. 2003) (cleaned up); *see Agilent Techs., Inc. v. Micromuse, Inc.*, 316 F. Supp. 2d 322, 327 (E.D. Va. 2004) (applying this reasoning to "conclude[] that Plaintiff's choice of forum is not entitled to substantial weight").

Notably, MSN Laboratories Private Limited has not litigated a single case in the Eastern District of Virginia. By contrast, it is a frequent litigant in Hatch-Waxman cases in the District of Delaware, which commonly include declaratory judgment counterclaims. *See, e.g.*, *Allergan Holdings Unlimited Co. v. MSN Labs. Priv. Ltd.*, C.A. No. 23-797 (D. Del. Oct. 27, 2023), Dkt. 11; *Celgene Corp. v. MSN Labs. Priv. Ltd.*, C.A. No. 23-699 (D. Del. Aug. 8, 2023), Dkt. 10; *Novartis Pharms. Corp. v. Alembic Pharms. Ltd.*, C.A. No. 22-1395 (D. Del. Dec. 16, 2022), Dkt. 33; *Intercept Pharms., Inc. v. MSN Labs. Priv. Ltd.*, C.A. No. 20-1214 (D. Del. Jan. 13, 2021), Dkt. 25.

By contrast, MSN has a presence in Delaware, through its wholly-owned subsidiary MSN Pharmaceuticals Inc., and its cause of action is tied to Delaware. The purported (but improper) October 13, 2023 "notice letter" that is the basis of this Hatch-Waxman declaratory suit, Compl. ¶ 29, indicates MSN Pharmaceuticals Inc. is the "U.S. Agent for MSN Laboratories Private Limited." Ex. 2 (MSN Letter) at 1. MSN Pharmaceuticals Inc. is a company incorporated in Delaware with a place of business in Piscataway, New Jersey. *Id.*; *Harmony Biosciences, LLC v. MSN Pharms. Inc.*, C.A. No. 23-1420-MN (D. Del. Dec. 11, 2023), Dkt. 1 ¶ 17. MSN Pharmaceuticals Inc. is a named defendant in the infringement suit brought by Bioprojet and

Harmony in the District of Delaware one business day after the present suit. *Harmony Biosciences, LLC v. MSN Pharms. Inc.*, C.A. No. 23-1420-MN (D. Del. Dec. 11, 2023), Dkt. 1.

Third, this Court lacks jurisdiction over a necessary or desirable party in the present suit. Harmony Biosciences LLC, a Delaware company, is the exclusive licensee of the patents-in-suit and the holder of NDA No. 211150 for WAKIX®. Harmony is engaged in the clinical development of WAKIX® and sells WAKIX® tablets in the United States. The Federal Circuit has held that the exclusive licensee is a necessary party in suits involving patents. *Aspex Eyewear, Inc. v. Miracle Optics, Inc.*, 434 F.3d 1336, 1344 (Fed. Cir. 2006) ("For the same policy reasons that a patentee must be joined in any lawsuit involving his or her patent, there must be joinder of any exclusive licensee."). This is true even in declaratory judgment suits. *See A123 Sys., Inc. v. Hydro-Quebec*, 626 F.3d 1213, 1217 (Fed. Cir. 2010) (a patent owner and exclusive licensee are required to bring a patent infringement suit together, and "an accused infringer must likewise join both the exclusive licensee and the patentee in a declaratory action"); *see also Apotex Inc. v. Gilead Scis., Inc.*, C.A. No. 18-06475, 2019 WL 1779582, at *5 (N.D. Cal. Apr. 23, 2019) (finding that an exclusive licensee is a required party in a Hatch-Waxman declaratory judgment action). Were this Court to rule the patents invalid, Harmony would lose all rights in the patents despite not having an opportunity to defend its interests in the litigation. *A123 Sys.*, 626 F.3d at 1221. The Federal Circuit has acknowledged that while an exclusive licensee and a patent owner may have "overlapping" interests, they are "not identical," particularly when these parties are unrelated, separate entities (as is the case here with patent owner Bioprojet SCR and exclusive licensee Harmony). *Id.* Moreover, a judgment in this case without Harmony would be inadequate because of the risk of inconsistent relief, as discussed in more detail below.

For the reasons stated above, plaintiff's choice of forum should be given no weight.

B. Transfer and Consolidation with Pending Cases in the District of Delaware Addressing the Same Patents Will Serve the Convenience of the Parties and Witnesses and Promote the Just and Efficient Resolution of the Issues.

Similarly, the second and third factors—the "convenience of the parties" and "witness convenience and access"—weigh in favor of transferring this case to Delaware. *Noetic*, 453 F. Supp. 3d at 845. Although "convenience of the parties and witnesses" are two separate factors in the § 1404(a) inquiry, courts often consider them together. *Id.* at 847. Because Delaware is far more convenient for the parties and their potential witnesses, the factors of party and witness convenience weigh heavily in favor of transfer. *See Van Dusen*, 376 U.S. at 622 (convenience should be considered with the purpose of "prevent[ing] the waste of time, energy and money and to protect litigants, witnesses and the public against unnecessary inconvenience and expense" (internal quotation marks omitted)). As an initial matter, MSN's complaint in the present action fails to include as parties Harmony, Bioprojet Pharma, and MSN Pharmaceuticals Inc., who are each parties to the Delaware action between MSN and Bioprojet SCR. MSN's decision to leave these parties out of their complaint does not change the fact that they have information relevant to this dispute, and the convenience of these entities and their witnesses should be taken into account.

Harmony, the NDA holder for WAKIX®, exclusive licensee of the patents-in-suit, and the company responsible for marketing and selling WAKIX® in the United States, is organized in Delaware and has a principal place of business in Plymouth Meeting, Pennsylvania, which is only 37 miles away from the District of Delaware. Ex. 4 (Google Maps printout). Delaware is a significantly more convenient venue for Harmony and Harmony employees who may be potential witnesses in this dispute regarding WAKIX®.

Delaware is also far more convenient for Bioprojet SCR, Bioprojet Pharma, and Harmony because they are already litigating against MSN and six other generic drug companies in that district on the same patents-in-suit. These related cases in Delaware will involve the same

witnesses from Bioprojet SCR, Bioprojet Pharma, and Harmony. Transferring the present declaratory judgment action will obviate the need for duplicative discovery efforts and travel by witnesses and corporate representatives to more than one venue. Transfer and consolidation or coordination will allow one court to schedule and control the parties' discovery and pretrial efforts while ensuring that the parties and witnesses are not subject to competing obligations in two different actions.

By contrast, MSN has not alleged that either Bioprojet SCR or MSN have any employees or other witnesses in this District at all. Where, as here, "the plaintiff files suit outside its home district, the convenience of the parties factors more prominently in the calculus." *Macronix Int'l Co., Ltd. v. Spansion Inc.*, C.A. No. 13-679, 2014 WL 934521, at *5 (E.D. Va. Mar. 10, 2014) (citing *Bluestone Innovations, LLC v. LG Elecs., Inc.*, 940 F. Supp. 2d 310, 316 (E.D. Va. 2013)). The fact that MSN has never previously litigated a case in this District but has frequently litigated in Delaware further demonstrates that this District is less convenient for MSN to litigate in than Delaware. *See, e.g.*, *Allergan Holdings Unlimited Co.*, C.A. No. 23-794, Dkt. 9; *Celgene Corp.*, C.A. No. 23-699, Dkt. 10; *Novartis Pharms. Corp.*, C.A. No. 22-1395, Dkt. 33; *Intercept Pharms., Inc.*, C.A. No. 20-1214, Dkt. 25. MSN cannot assert any legitimate interest in having the Eastern District of Virginia—rather than the District of Delaware—resolve this dispute.

Accordingly, both party and witness convenience weigh heavily in favor of transfer.

C. Transfer to the District of Delaware Will Serve the Interest of Justice by Eliminating the Risk of Inconsistent Judgments and Promoting Judicial Economy, as All Related Actions Can Be Litigated and Resolved Together.

The final factor when considering transfer under § 1404(a) is "the interest of justice." *Noetic*, 453 F. Supp. 3d at 845. Analysis of this factor encompasses considerations such as "pendency of a related action" and "the ability to join other parties." *Coors Brewing Co. v. Oak Beverage, Inc.*, 549 F. Supp. 2d 764, 773 (E.D. Va. 2008). Ultimately, the interest of justice factor

"encompasses public interest factors aimed at systemic integrity and fairness, with the most prominent considerations being judicial economy and the avoidance of inconsistent judgments." *Sunstone Info. Def., Inc. v. F5 Networks, Inc.*, C.A. No. 21-50, 2021 WL 5804571, at *6 (E.D. Va. Dec. 7, 2021) (internal quotation marks omitted). Transfer to Delaware will promote the interest of justice by providing for a single consistent and efficient judicial resolution of all patent infringement and validity issues surrounding WAKIX®, as well as a forum where Harmony, the exclusive licensee, can be joined.

Here, where multiple related actions against MSN as well as six other groups of generic manufacturers are pending in the District of Delaware before Judge Noreika, the public interest in avoiding inconsistent judgments and promoting judicial economy strongly supports transfer of this case to Delaware. *See U.S. Ship Mgmt., Inc. v. Maersk Line, Ltd.*, 357 F. Supp. 2d 924, 937 (E.D. Va. 2005) ("The interest of justice weighs heavily in favor of transfer when related actions are pending in the transferee forum."). The same issues in the present action will be addressed in the three Delaware actions—they involve the same parties (among others), the same patents-in-suit, and the same legal issues of validity and infringement, and they will be tried before the same judge. If this action is transferred to Delaware, Bioprojet SCR will seek consolidation of this action with the related Delaware action between Bioprojet SCR and MSN, as well as the two related actions against six other generic companies involving the same patents-in-suit. Thus, transfer will avoid the possibility of inconsistent judicial determinations concerning discovery issues, claim construction, infringement, and validity of the patents-in-suit.

Transfer will also avoid the unnecessary waste of resources for the courts that would occur if these cases were to proceed separately at the same time in two different venues. *See Cont'l Grain*, 364 U.S. at 26 ("To permit a situation in which two cases involving precisely the same

issues are simultaneously pending in different District Courts leads to the wastefulness of time, energy, and money that § 1404(a) was designed to prevent."). Given the common legal and factual issues at play in this case and the cases against MSN and six other generic manufacturers pending in Delaware, the most practical course of action is to transfer this case to the District of Delaware. *See Bluestone Innovations*, 940 F. Supp. 2d at 319 (finding that "interest of justice factor weigh[ed] heavily in favor of transfer" of venue from the Eastern District of Virginia where patent holder was currently a party to a case in the Northern District of California asserting the same patent, the cases would likely be consolidated, and trying the cases separately would create serious risk of inconsistent results).

Although courts in this district have considered the "first-to-file" rule as a "component of the interest of justice" prong in the transfer analysis, the fact that MSN filed this action one business day before Bioprojet and Harmony sued MSN in Delaware should be accorded no weight. *See Byerson v. Equifax Info. Servs., LLC*, 467 F. Supp. 2d 627, 635 (E.D. Va. 2006). Exceptions to the first-to-file rule include "forum shopping" and "anticipatory suits." *SZ DJI Tech. Co. Ltd. v. Bell Textron Inc.*, C.A. No. 23-931, 2023 WL 6541848, at *7 (E.D. Va. Oct. 6, 2023). Both are applicable here.

Here, MSN engaged in forum shopping by bringing a suit with no apparent connection to this district, and purposefully avoided naming exclusive licensee and NDA holder Harmony because it is a Delaware company. Harmony is a necessary or desirable party because it is the exclusive licensee of the patents-in-suit, the NDA holder for WAKIX®, and is engaged in the clinical development, marketing and sales of the branded drug. *See Aspex Eyewear*, 434 F.3d at 1344; *A123 Sys.*, 626 F.3d at 1217. MSN's forum shopping and the "[in]ability to join other parties" to the present suit favor transferring the case in the interest of justice. *Coors Brewing Co.*, 549 F.

Supp. 2d at 773; *see also SZ DJI Tech. Co*., 2023 WL 6541848, at *8; *Pragmatus AV, LLC v. Facebook, Inc*., 769 F. Supp. 2d 991, 997 (E.D. Va. 2011) ("Left unchecked, allowing lawsuits with such a minimal connection to the district to go forward here would result in docket overloads, unfairly slowing the cases for parties with genuine connections to this district.").

Moreover, this suit is anticipatory in nature. "An anticipatory filing is improper when it attempts to exploit the first-to-file rule by securing a different venue from one that the filer's adversary would be expected to choose." *SZ DJI Tech. Co.*, 2023 WL 6541848, at *7. The Hatch-Waxman Act prohibits an ANDA applicant's preemption of a patentee's choice of forum until the 45-day period has expired. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa). As explained in Section II.A above, the 45-day period has not run because MSN has not given proper notice.

By bringing this action prior to expiration of the 45-day period, MSN filed an anticipatory action, knowing that Bioprojet SCR and Harmony would have chosen to file suit in Delaware, where they already had filed two related Hatch-Waxman suits on the same patents against six other generic companies. Under these circumstances, the Court should not apply the first-to-file rule. Indeed, some courts have even dismissed anticipatory Hatch-Waxman declaratory judgment suits for failing to first provide proper notice as required by the statute. *See Paddock Labs., Inc. v. Ethypharm S.A.*, C.A. No. 09-3779, 2011 WL 149860, at *4 (D.N.J. Jan. 18, 2011) (refusing to exercise its discretionary jurisdiction over Hatch-Waxman declaratory judgment suit because it "is improper to require Defendants to respond to a lawsuit when the 45 day period has not lapsed," and noting that "the purpose of allowing a declaratory judgment in the Hatch-Waxman Act was to prevent NDA holders from putting off resolution of the suit and harassing ANDA filers with scare tactics, not to require NDA holders to suffer a lawsuit when they still have the opportunity to bring their own").

III. Alternatively, This Action Should Be Stayed Until the District of Delaware Actions Are Resolved.

Should this Court decline to transfer this action to Delaware, it should exercise its "broad discretion to stay proceedings as an incident to its power to control its own docket" to stay proceedings during the pendency of the corresponding Delaware action between Bioprojet SCR and MSN. *See Clinton v. Jones*, 520 U.S. 681, 706 (1997). Otherwise, the parties will have to proceed with cases covering the same patents-in-suit and same legal issues at the same time in two different venues. That scenario would be a waste of both party and judicial resources that outweighs any inconvenience MSN might suffer from a pause in proceedings. Staying proceedings would conserve judicial resources and simplify the issues in this case.

Granting a stay at this early stage would present no practical or logistical obstacles to the parties or the Court. The Court has yet to set a case schedule, discovery has not begun, and no trial date has been set. Furthermore, MSN would not be unduly prejudiced or tactically disadvantaged by a stay. MSN claims that it filed this action to avoid legal uncertainty stemming from seeking approval to market a generic copy of WAKIX® prior to the expiration of Bioprojet SCR's patents. Compl. ¶¶ 32, 34. If this action is stayed while the related Delaware action proceeds, each of the validity and infringement issues for which MSN seeks certainty will be addressed in the District of Delaware.

Staying this action so that the parties may litigate to completion of the Delaware action also would not prejudice MSN because FDA cannot approve MSN's ANDA until at least August 14, 2026 due to orphan drug exclusivity for treatment of excessive daytime sleepiness in patients with narcolepsy. Ex. 1 (WAKIX® Orange Book Listing).

CONCLUSION

For these reasons, the Court should transfer this case to the District of Delaware under 28 U.S.C. § 1404(a) or alternatively stay it pending resolution of the parallel Delaware action.

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Respectfully submitted,

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